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10/524723

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



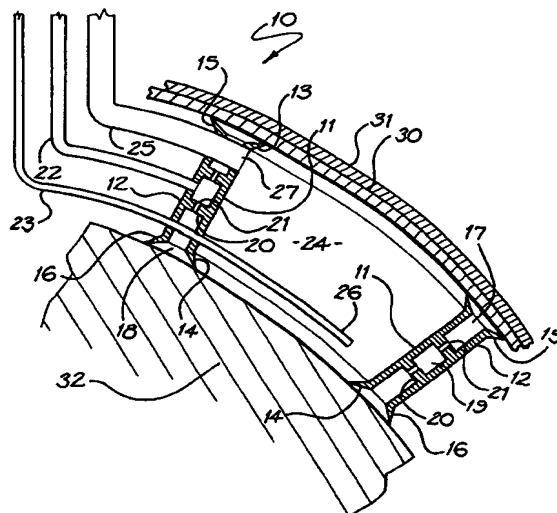
(43) International Publication Date  
4 March 2004 (04.03.2004)

PCT

(10) International Publication Number  
**WO 2004/017877 A1**

- (51) International Patent Classification<sup>7</sup>: **A61F 9/007**, **A61M 3/02**
- (21) International Application Number: **PCT/AU2003/001084**
- (22) International Filing Date: **22 August 2003 (22.08.2003)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:  
**2002 951 307**      **22 August 2002 (22.08.2002)**      **AU**
- (71) Applicant (for all designated States except US): **MILVELLA PTY LIMITED** [AU/AU]; 10 Melrose Street, EPPING, New South Wales 2121 (AU).
- (71) Applicants and  
(72) Inventors: **NEILSON, Geoffrey, James** [AU/AU]; 7A Hillcrest Avenue, Epping, New South Wales 2121 (AU). **MALOOF, Anthony** [AU/AU]; PO Box 155, Kingsford, New South Wales 2032 (AU). **MILVERTON, Edward, John** [AU/AU]; Unit 5105, 343 Pitt Street, Sydney, New South Wales 2000 (AU).
- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.**
- (84) Designated States (regional): **ARIPO** patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), **Eurasian** patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), **European** patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), **OAPI** patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**  
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **DOUBLE-SIDED SURGICAL IRRIGATOR**



(57) Abstract: A surgical irrigation device (10) consists of a continuous outer wall (12) and a continuous inner wall (11) which are held apart and inter-connected by one or more spacers (20). The upper edges (13), (15) of the inner and outer walls (11), (12) define an upper vacuum channel (17) and the lower extremities (14), (16) of the inner wall (11) and outer wall (12) a lower vacuum channel. A vacuum tube (22) leads from outside the body (10) into the space between the inner and outer walls (11), (12). An irrigation tube (23) passes from outside of the body (10), through both the inner walls (11), (12) so as to terminate within the central space defined by the interior wall (11) and an aspiration tube (25) which originates externally to the body passes through both the inner and outer walls (11), (12) at a different location to the irrigation tube (23).

WO 2004/017877 A1

## DOUBLE-SIDED SURGICAL IRRIGATOR

### FIELD OF THE INVENTION

5           The present invention pertains to surgical irrigation devices and more particularly to an irrigation device which is adapted to isolate a volume in the human body which volume lies between two tissues.

### BACKGROUND OF THE INVENTION

10           Some surgical and therapeutic treatments of the human eye require particular areas of ocular tissues to be treated with generally toxic fluids. It is therefore highly desirable to limit the areas which are contacted by these fluids. In particular it is desirable to isolate adjacent surfaces or areas which lie on tenon's capsule and the sclera.

### SUMMARY OF THE INVENTION

15           Accordingly, there is provided an irrigation device comprising a body having a continuous outer wall and a continuous inner wall which are held apart and inter-connected by one or more perforated spacers. The upper edges of the inner and outer walls may each comprise an upper seal. Together, these upper seals may co-operate to define an upper vacuum channel.

20           The lower extremities of the inner wall and outer wall may also terminate in sealing surfaces which together form a lower vacuum channel. A vacuum tube may lead from outside the body into a space between the inner and outer walls. Vacuum drawn through this tube is distributed evenly about the upper and lower vacuum channels.

25           An irrigation tube may pass from outside of the body, through both the exterior and interior walls so as to terminate within the central space defined by the interior wall. An aspiration tube which originates externally to the body may

also pass through both the interior and exterior wall at a different location to the irrigation tube.

In a preferred embodiment of the invention, the irrigation tube extends into the central space defined by the interior wall so that it is distant from an aspiration port formed in the interior wall.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be more readily understood and put into practical effect, reference will now be made to the accompanying drawings in which:-

- 10        Fig. 1 is a schematic cross-sectional view of an irrigation device according to one embodiment of the invention located between tenon's capsule and the sclera;
- Fig. 2 is a top plan view of the device depicted in Fig. 1;
- Fig. 3 is a top plan view of a double-sided irrigation device according to another embodiment of the invention;
- 15        Fig. 4 is a bottom plan view of the device depicted in Fig. 3 illustrating the location of irrigation, aspiration and vacuum tubes;
- Fig. 5 is a cross-section through lines 5-5 of Fig. 3;
- 20        Fig. 6 is a cross-section through lines 6-6 of Fig. 4; and
- Fig. 7 is a view similar to Fig. 5 of a further embodiment of the invention illustrating separate vacuum control of the upper and lower vacuum channels.

#### PREFERRED EMBODIMENTS OF THE INVENTION

- 25        As shown in Fig. 1, a double-sided irrigator 10 according to one embodiment of the invention comprises a continuous inner wall 11 and a continuous outer wall 12. In this instance, the inner and outer walls 11, 12 are

approximately the same height and spaced apart from one another equally about their entire periphery. The continuous inner wall 11 terminates at its upper end with an upper seal 13 and at its lower end with a lower seal 14. Similarly, the outer wall 12 terminates at its upper end with an upper seal 15  
5 and at its lower end with a lower seal 16. Together, the upper seals 13, 15 define an upper vacuum channel 17. Similarly, the lower seals 14, 16 define a lower vacuum channel 18.

In this embodiment, each of the seals 13, 14, 15, 16 comprises an enlarged portion, lip or flange over which the pressure associated with sealing  
10 is distributed. This minimises the contact pressure and increases the sealing area and effectiveness in those areas where the device contacts tissue.

The space 19 between the inner and outer walls 11, 12 defines a manifold which is adapted to supply equal vacuum pressure to the upper and lower vacuum channels 17, 18. In order that the device be mechanically  
15 stable, one or more spacers 20 are interposed and preferably affixed to both the interior surfaces of the inner and outer walls 11, 12. The spacers 20 may be in the form of continuous ring-like structures having perforations 21 which allow the internal pressure to be equalised on either side of the one or more spacers.

20 Simultaneous sealing between two generally parallel tissues is accomplished by delivering vacuum pressure to the interior 19. This is done from a vacuum tube 22 which originates outside of the outer wall 12 and terminates and communicates fluidically with the interior 19 between the walls. Once the device is sealed in place, a fluid may be introduced through an  
25 irrigation tube 23 which originates outside of the exterior wall 12 and passes through both the exterior and interior walls 11, 12 before terminating within the central space 24 surrounded by the interior wall 11.

An aspiration tube 25 is also provided. The aspiration tube 25 passes through the exterior and interior walls 11, 12 and terminates in the central space or cavity 24. In a preferred embodiment, the irrigation tube extends at least partially across the central space or cavity 24 so that the distance  
5 between the end 26 of the irrigation tube and the end 27 of the aspiration tube are well separated from one another. This provides the longest practical minimum flow path between the two ends 26, 27.

It will be appreciated that the device as depicted in Figs. 1 and 2 is capable of a wide variety of uses. In the particular embodiment depicted, the  
10 device is conveniently positioned between tenon's capsule 30 (the lining of the conjunctiva 31) and the surface of the sclera 32. It will be appreciated that a device of this kind has a wide variety of uses where it is desirable to isolate a volume between two surfaces or two tissues, particularly where that volume is subject to irrigation and aspiration and more particularly where it is important to  
15 maintain that volume as a constant without increasing the pressure within it. It will be appreciated that for surgical or therapeutic procedures of this kind the general thickness of the body will be no more than about 2mm and that the maximum dimension and plan view (corresponding to the diameter of a circle) will be about 15mm.

20 As shown in Fig. 3, a double-sided irrigation device may define different sealing profiles with its upper and lower vacuum channel 41 in this example is essentially circular. The major portion of the upper vacuum channel 42 is generally circular and a minor portion 43 is rebated. Note that the inner 44 and outer 45 upper seals maintain a uniform spacing just as the inner 46 and outer  
25 47 lower seals are uniformly spaced throughout.

As shown in Fig. 4, a device of the type depicted in Fig. 3 may be provided with an irrigation tube 48 which terminates within the central cavity.

An aspiration tube 49 is also provided. In this example, a single vacuum tube 50 terminates between the inner and outer walls and thus introduces vacuum into a central manifold 55 which is located between the inner and outer walls.

As shown in Fig. 5, the upper vacuum channel 42 and the lower vacuum channel 41 are seen to have different configurations. In this example, spacers 51 are interposed between the inner and outer walls where the upper and lower channels coincide. Spacers 51 may be provided with through holes 52 to allow vacuum pressure to be communicated evenly between the upper and lower vacuum channels 41, 42.

As shown in Fig. 6, the spacers 51 may be provided as arrays of discrete blocks or other shapes with no overlap between the spacers 51 of the upper tier 53 and those of the lower tier 54. This is one way of providing sufficient rigidity in the vacuum channel area while still allowing vacuum pressure to be communicated evenly between the upper and lower vacuum channels.

As shown in Fig. 7, the upper vacuum channel 42 and lower vacuum channel 43 may be fluidically disconnected and supplied with separate vacuum sources 60, 61. In this way, the vacuum to the upper and lower channels 42, 43 may be controlled independently.

The device may be used, for example, in trabeculectomy procedures (for glaucoma) to prevent adhesion of the tissues to the filtering bleb. In preferred embodiments, the device is provided as a disposable instrument, being flexible and injection moulded from an elastomer. However, rigid moulded or machined devices are also contemplated.

It will be appreciated that in addition to sealing a defined profile a flexible device with the same top and bottom sealing profiles may be formed into a

shape between the tissues, prior the applying the vacuum thus sealing a shape defined by the user at the time that the vacuum is applied.

It is also envisaged that the aspiration tube or tubes may be optionally connected to a sealed drainage bag for simple disposal of the irrigation liquid  
5 which provides for safer handling of toxic chemicals such as cytotoxic drugs.

Although the invention has been disclosed with reference to particular details of construction it will be appreciated that these have been provided by way of example and not as limitations to the scope or spirit of the invention. Specifically, the device has been disclosed, (for example in Fig. 2) as being  
10 generally circular. It will be appreciated that the device may be provided in any variety of external confirmations including, without limitation, circular, oval, crescent or irregular confirmations. Various other modifications may be made to the irrigation device without departing from the scope and ambit of the invention.

**CLAIMS:**

1. A surgical irrigation device comprising a body having a continuous outer wall and a continuous inner wall which are held apart by one or more spacers, the upper extremities of the inner and outer walls each having an upper sealing surface which together form an upper vacuum channel and the lower extremities of the inner and outer walls each having a lower sealing surface which together form a lower vacuum channel.
2. A surgical irrigation device according to claim 1 and further including a vacuum tube leading from outside the body into the space between the inner and outer walls, and where a vacuum drawn through the vacuum tube is distributed evenly about the upper and lower vacuum channels.
3. A surgical irrigation device according to claim 1 and further including an irrigation tube leading from outside of the body, through both the exterior and interior walls so as to terminate within the central space defined by the interior wall.
4. A surgical irrigation device according to claim 3 and further including an aspiration tube leading from outside of the body through both the interior and exterior walls and terminates at a different location to the irrigation tube.
5. A surgical irrigation device according to claim 3 wherein the irrigation tube extends into the central space defined by the interior wall so that it is distant from an aspiration port formed in the interior wall.



6. A surgical irrigation device according to claim 1 wherein the spacers are perforated.
7. A surgical irrigation device according to claim 1 wherein the spacers comprise first and second tiers of spaced apart spacers with no overlap between the spacers of the first tier and the spacers of the second tier.
8. A surgical irrigation device according to claim 1 wherein there is a boundary between the upper vacuum channel and the lower vacuum channel and further including a first vacuum tube leading from outside the body into the upper vacuum channel and a second vacuum tube leading from outside the body into the lower vacuum channel.
9. A surgical irrigation device according to claim 1 wherein the lower vacuum channel and the upper vacuum channel are of the same configuration.
10. A surgical irrigation device according to claim 9 wherein the lower vacuum channel and the upper vacuum channel are circular in plan.
11. A surgical irrigation device according to claim 1 wherein the lower vacuum channel is circular in plan and the major portion of the upper vacuum channel is circular in plan and the minor portion is rebated.
12. A surgical irrigation device according to claim 1 wherein the upper extremities of the inner and outer walls and the lower extremities of the inner and outer walls comprised enlarged lips.

1/3

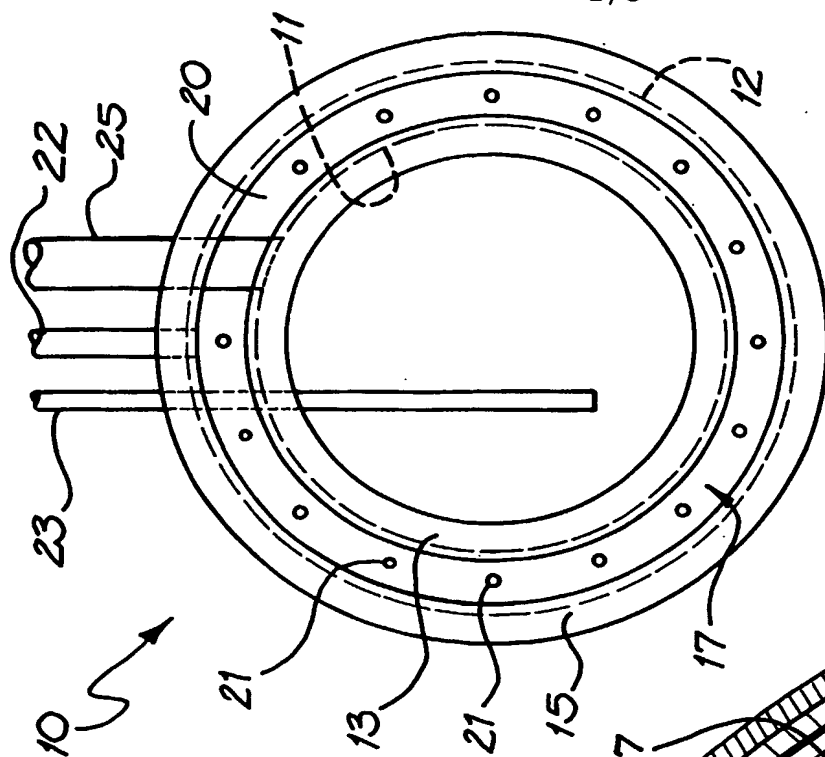


FIG. 2

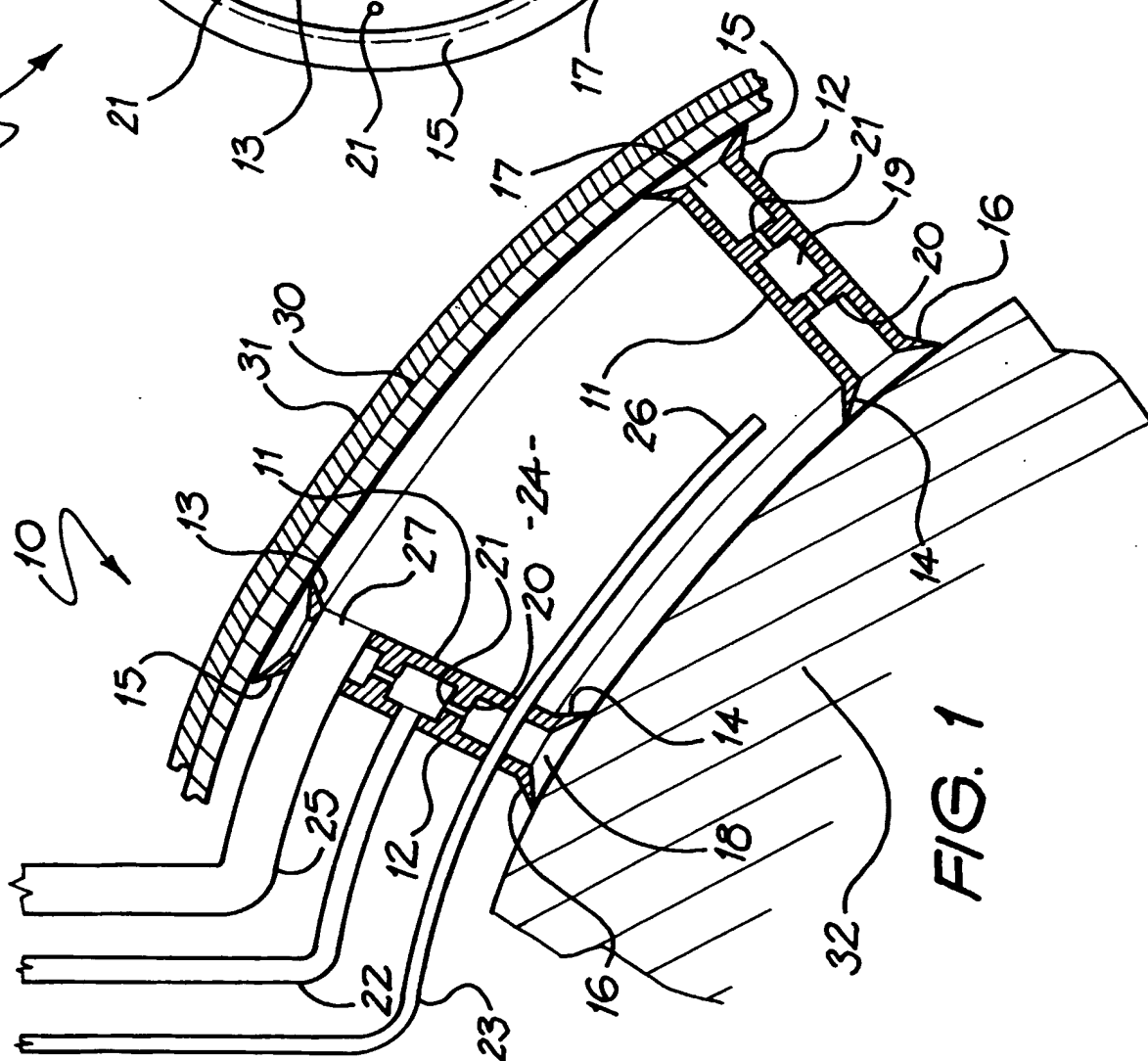
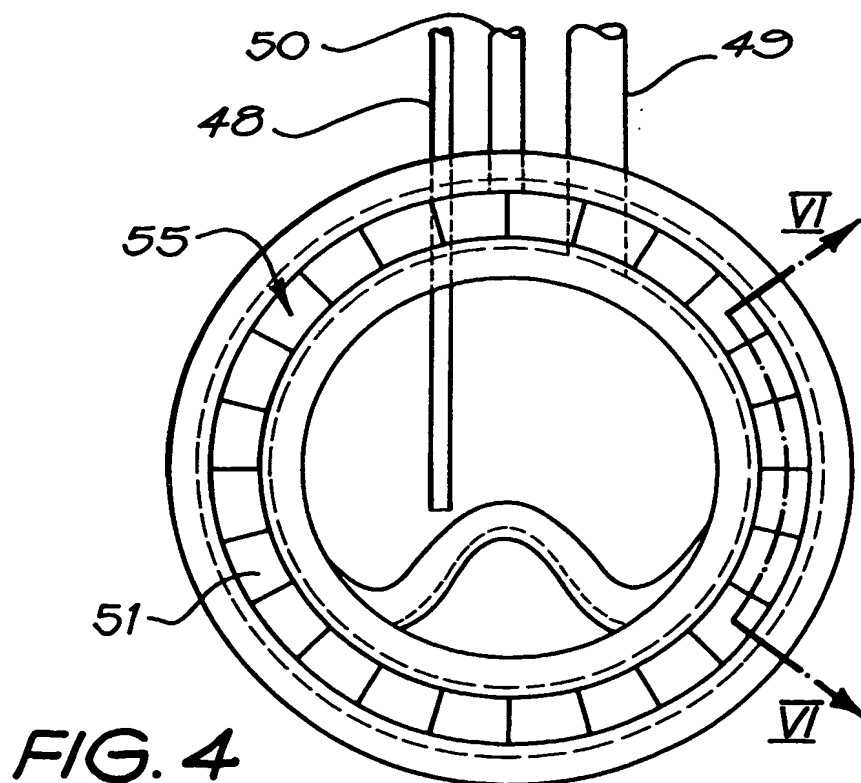
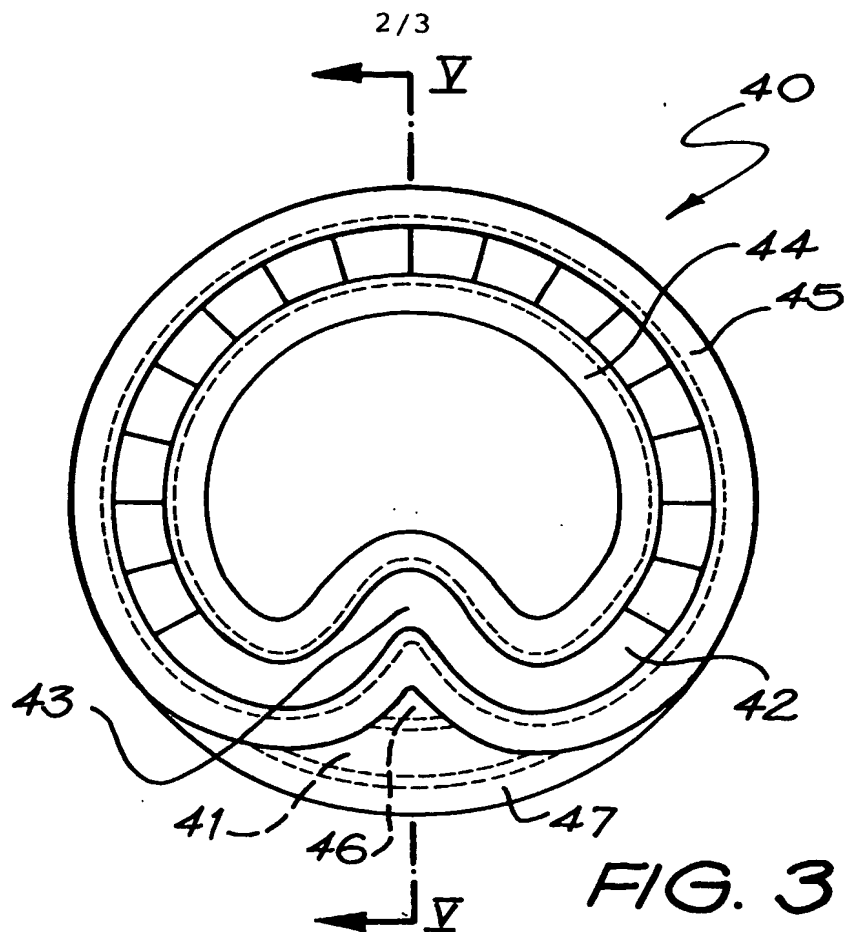
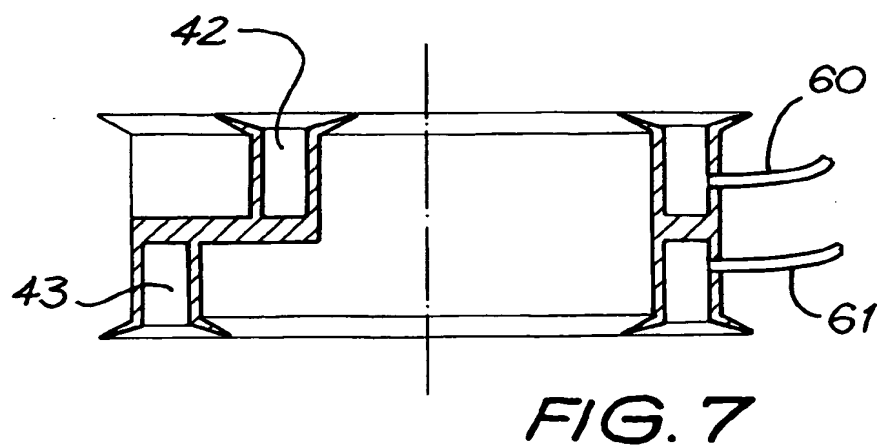
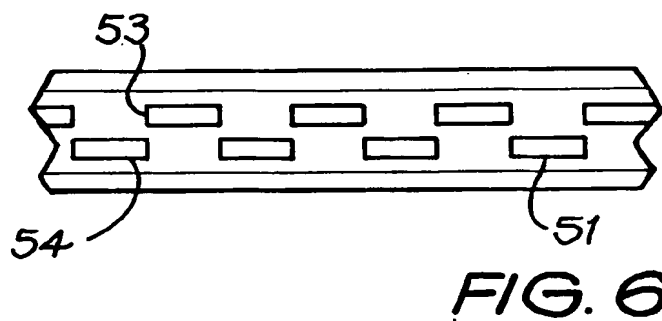
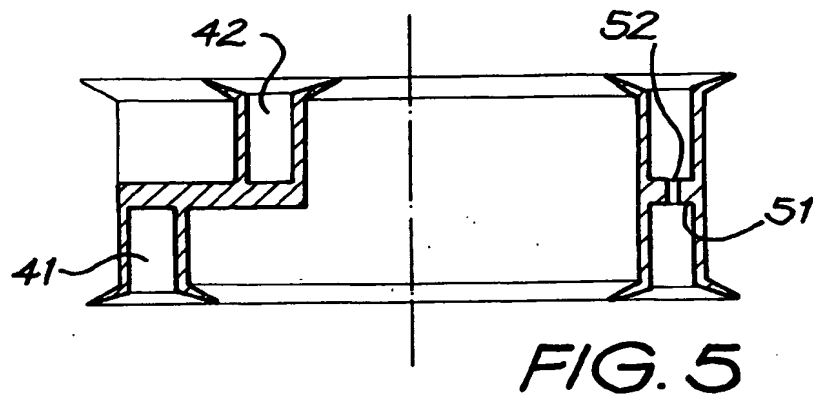


FIG. 1



3 / 3



# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/AU03/01084**

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>				
Int. Cl. <sup>7</sup> : A61F 9/007 A61M 3/02				
According to International Patent Classification (IPC) or to both national classification and IPC				
<b>B. FIELDS SEARCHED</b>				
Minimum documentation searched (classification system followed by classification symbols)				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI + keywords: A61M/IC A61F-009/IC vacuum suction channel tube irrigat wash seal isolate tissue eye and similar terms				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
A	US 5108412 A (KRUMEICH et al) 28 April 1992 Whole document			
A	US 2001/0021844 A1 (KURTZ et al ) 13 September 2001 Whole document			
A	WO 98/18517 A (HELLENKAMP) 7 May 1998			
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex				
<p>* Special categories of cited documents:</p> <table style="width: 100%;"> <tr> <td style="width: 50%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p> </td> </tr> </table>			<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p>
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Date of the actual completion of the international search 3 October 2003		Date of mailing of the international search report 10 OCT 2003		
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer  Sue Thomas Telephone No : (02) 6283 2454		

# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/AU03/01084**

<b>C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
<b>Category*</b>	<b>Citation of document, with indication, where appropriate, of the relevant passages</b>	<b>Relevant to claim No.</b>
P,A	WO 03/022191 A1 (NEILSON et al ) 20 March 2003 Whole document	
P,A	WO 03/002010 A1 (LAHAYE) 9 January 2003 Whole document	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU03/01084

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	5108412	DE	3838253		
WO	9818517	AU	51630/98	EP	1014903
		US	5772675	US	6042594
				US	6387107
US	2001021844	EP	993814	JP	2000116694
				WO	2083018
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